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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,734	09/29/2000	Charles Joel Arntzen	P00245US D	1914

7590 04/20/2005

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/676,734

Applicant(s)

ARNTZEN ET AL.

Examiner

Cynthia Collins

Art Unit

1638

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) a set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 73-75, 83, 84 and 98-104.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 0105  
13. ☒ Other: PTO-892 Notice of References cited.

*Cynthia Collins* 4/12/05

Continuation of 11. does NOT place the application in condition for allowance because: the specification does not reasonably provide enablement for expressing in all plants recombinant viral antigen proteins obtained from all animal viruses at a level sufficient to induce an immune response upon oral administration of said plant to an animal or at a level of at least 43 ng/mg or higher of total soluble protein. The disclosure of generally known materials and methods used in the prior art for plant transformation and heterologous protein expression in plants does not provide sufficient guidance for one skilled in the art to practice the full scope of the claimed invention without undue experimentation because the expression in a plant of candidate antigens obtained from any and all animal viruses at a level sufficient to induce an immune response upon oral administration of said plant to an animal or at a level of at least 43 ng/mg or higher of total soluble protein would require further guidance with respect to how to use generally known materials and methods for plant transformation and heterologous protein expression to achieve such levels of expression for each type of candidate antigen. The five published journal articles submitted also do not support the enablement of the full scope of the claims. Four of the five articles (May G.D. et al. 1995, Ganapathi, T.R. et al. 2001, Walmsley A.M. et al. 2003 and Haq T.A. et al. 1995) are not directed to the expression in a plant of animal viral antigen proteins. With respect to the single article directed to the expression in a plant of an animal viral antigen protein (Tacket C.O. et al. 2000), Tacket C.O. et al. does not support the enablement of the full scope of the claimed invention because the Norwalk virus capsid protein antigens expressed by Tacket C.O. et al. were not expressed in plants using the disclosed methods, i.e. the specification does not provide guidance that this specific combination of elements (Norwalk virus capsid protein coding region with a modified 5'end fused to the TEV 5'-UTR operably linked to a patatin promoter and nos terminator) would result in expression in a potato plant of Norwalk virus capsid protein antigens at the claimed levels.

Applicants assertion that the outstanding rejections under the judicially created doctrine of obviousness-type double patenting will be addressed when the Examiner indicates that the claims are allowable is also acknowledged.

Continuation of 12. The IDS filed January 18, 2005 was not considered because it did not comply with the requirements of 37 CFR 1.97 (d)(1).